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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/194,165	05/11/1999	LYNN PERKES	09143/005001	2876

7590

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EXAMINER

PATTEN, PATRICIA A

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 08/13/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/194,165

Applicant(s)

Perkes, L.

Examiner

Patricia Patten

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 19, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-77 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 19 6) ☐ Other:

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DETAILED ACTION

RCE Practice

A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 7/19/02 has been entered.

Claims 48-77 are pending in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Trademarks

The use of the trademark has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

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Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

Claims 48-77 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' arguments presented 7/19/02 were fully considered, and relevant arguments pertaining to the previous rejections under 35 U.S.C. 112 First paragraph will be answered.

Applicants principal argument is that

"...a person having ordinary skill in the art reading Applicant's specification would have been able to make and use the presently claimed invention without undue experimentation....by combining a grape seed extract with a grape skin extract and at least one enzyme such that either (a) the grape seed extract

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is 3.3 percent or more of the supplement, or (b) the grape seed extract and the grape skin extract combined is 32 percent or more of the supplement" (Arguments, p. 6).

However, Applicants still have not provided information regarding what grape skin/grape seed extracts the claim is referring to and how to go about making such extracts.

As stated in previous Office Actions, the art of phytochemistry is unpredictable with regard to plant extracts. Applicants use the term 'extract' broadly without defining exactly what extracts the claim encompass. Plants, and fruits and seeds thereof, are intricate living organisms which inherently possess an enormously diverse array of potential pharmacological ingredients. Just recently has the scientific community begun examining plants (as well as parts thereof) to evaluate their phytochemical constituents for medicinal purposes.

It is well known in the art that polarity of solvents plays a key role in determining the final product obtained by an extraction. However, because many phytochemicals remain undiscovered, the skilled artisan has to make his best educated guess as to what types of phytochemicals will be successfully extracted with a solvent of a particular polarity. Often times, unless the constituents in a particular plant extract have been well evaluated and documented in the literature, the skilled artisan must adhere to trial and error protocols in order to quantitatively determine phytochemical constituents present

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in samples obtained from respective extraction procedures. These procedures are common when, for example, a plant or part thereof has been documented in the literature as possessing some medicinal quality. The skilled artisan will attempt numerous extraction protocols in attempt to isolate the particular ingredient which has this medicinal quality. Typically, beginning with the first crude extraction, it is a guess as to whether or not the extract will possess the inherent medicinal quality. Take for example, the grape, *Vitis vinefera*. If this fruit was documented in the literature as having a particular medicinal qualities, the skilled artisan may feel the need to extract and isolate the medicinally beneficial ingredient.

First, the skilled artisan would need to ascertain if the active ingredient is found on the inside of the fruit; i.e., pulp or juice, or if alternatively, the active ingredient was found in the skin of the fruit. Thus, a first 'extract' may be obtained via pressing the fruit to obtain the juice and pulp of the fruit. The pulp and juice of the fruit would constitute a first product ('extract') with many various cell constituents. Of course, a determination would need to be made of if the extract, in this case, the pulp and the juice, actually possess the medicinal qualities as previously documented. If for example, the pulp and the juice of the grape did not prove to possess the documented medicinal quality, the skilled artisan would then test the skin of the grape for said quality (commonly, prior to solvent extraction, homogenization of the solids occurs via blending or vortexing). If the skin of the grape actually possessed the documented quality, the skilled artisan may

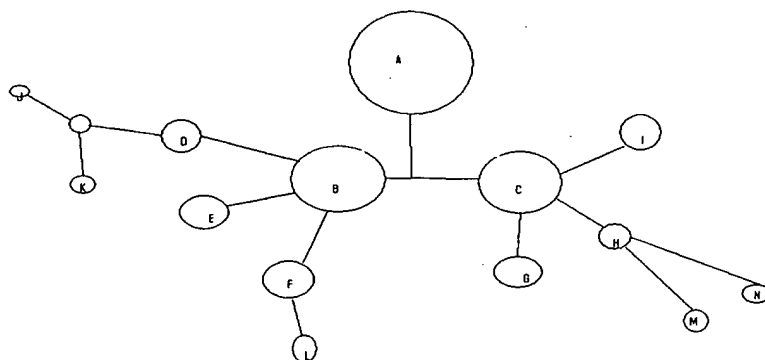
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then attempt to purify the ingredient further. Then, the skilled artisan will, by trial and error, attempt to perform step-wise extractions to isolate the active ingredient. If the first extraction attempt with a particular solvent fails, another solvent will be tried. Thus, beginning with the initial extraction, a first product is yielded which was extracted with the solvent, and a second product is yielded which remains because it did not possess a similar polarity to the solvent.

Each successive extraction yields different products due to the exclusion of ingredients based on the polarity of the solvents solvating constituents with similar polarities. Subsequently, the properties of each respective product would need to be evaluated for efficacy.

The following is an illustrative example of the many products which may be produced by different successive extraction protocols:

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In this example, assume that A= the initial water extract from a homogenized sample of grape. The water extract from the grape is then subjected to a methanol/water extraction to form products B (soluble with methanol) and C (more soluble with water). Product C is then extracted in a separatory funnel with three organic solvents: chloroform, benzene and ethyl ether to form products G, H and I which solvate with the respective solvents based on the polarity of the inherent constituents. Product H, which we will assume is the product obtained in the benzene fraction, is extracted again in a separatory funnel with benzene and methanol to remove any residual methanol-soluble constituents. The additional circles represent extractions which may be done to obtain different products, using similar solvents as discussed

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previously, or entirely different solvents. Consequently, the properties of each respective product would need to be evaluated for pharmacological efficacy. This representation is indicative of the vast array of distinct products which may be obtained due to the enormity of possible extraction permutations.

Additionally, according to the Stedman's dictionary 27th Ed, the term 'extract' means 'A concentrated preparation of a drug obtained by removing the active constituents of the drug with suitable solvents...' (Please see definition provided). Thus, purification of any of these products in the illustrative example to yield a specific phytochemical would constitute an 'extract' judging from the definition provided by Stedman's Medical Dictionary. Therefore, resveratrol, a phytochemical inherent in grapes, is deemed to be an 'extract' of grapes since it is obtained by the process outlined in Stedman's. Therefore, each respective phytochemical found within grapes constitutes an extract once it is 'extracted' away from the rest of the grape's constituents. Here, the unpredictability with regard to the term 'extract' in the claims has grown exponentially.

Each product obtained from an extraction is unpredictable in nature. Even the most skilled of artisans would need to quantify each product for constituents as well as medicinal efficacy. Unpredictability with regard to plant extracts has been well documented in the art. Revilla et al. for example (1998) showed that the slightest variations in polarity of solvent and reaction time upon grape extraction, provided

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respective products with unique characteristic properties (See Tables 1, 2, 4, 5, 6 and 7). In turn, each product would possess varying pharmacological properties based upon their respective phytochemical constituents.

The preceding is evidence that the mere recitation of the term 'extract' does not provide the skilled artisan with the information needed to make the claimed invention. On the contrary, the skilled artisan, lacking information with regard to exactly what extract Applicants intend, would necessarily need to perform tedious trial and error protocols without expectation of success.

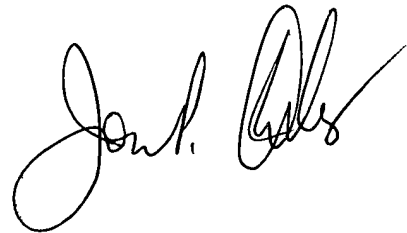
No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Jon P. Weber', with a stylized flourish at the end.

Jon P. Weber, Ph.D.
Primary Examiner